



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/559,681

12/06/2005

Lev Davidovich Rasnetsov

U 016055-9

3010

140

7590

01/07/2009

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/559,681 | Applicant(s) RASNETSOV ET AL. | |
| | Examiner SAMIRA JEAN-LOUIS | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-10 are currently pending in the application.

Applicant's election with traverse to various groups in the reply filed on 10/24/08 is acknowledged. The traversal is on the ground(s) that the claims relate to a single general inventive concept. Applicant argues that the prior art reference RU 2 196 692 discloses the use of fullerene derivatives containing a single moiety of X attached to the fullerene nucleus as a result of a mono-addition of an aminocarboxylic acid whereas the compound of the instant invention is a compound containing 2 to 12 moieties X separately attached to the fullerene nucleus as a result of poly-addition of 2 to 12 moieties of an aminocarboxylic acid. Thus, in this instance, these species are distinct and therefore would not read on applicant's invention. As a result, the Examiner has reconsidered the restriction and species election requirement given that the claims relate to a common general inventive concept. Consequently, the restriction and species election requirement is hereby withdrawn.

Claims 1-10 are therefore examined on the merits herein.

IDS

The information disclosure statement filed on December 06, 2005 (specifically items AF, AG, AH, and AJ) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is

Art Unit: 1617

presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. They have been placed in the application file, but only the information referred to therein in the abstract and the claims of said references have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claims 1-10 are particularly vague and indefinite given that applicant is claiming an agent which comprises a water soluble compound of fullerene polycarboxylic anion (**in sentences 1-2 of claim 1**). Given that applicant is claiming an agent, a single entity, the Examiner contends that such claims are indefinite since a single molecule cannot further contain another compound. As a result, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claims are unable to be examined as disclosed given that the scope of the claimed subject

Art Unit: 1617

matter would not be able to be determined by one of ordinary skill in the art.

However, for the purpose of examination, Examiner will construe that the stated agent is a compound selected from a water soluble fullerene polycarboxylic anionic compound of the general formula: $C_{60}H_n[NH(CH_2)_mC(O)O]_n$.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claims 1-10 are particularly vague and indefinite given that applicant is claiming an agent which comprises a water soluble compound of fullerene polycarboxylic anion of the general formula: $C_{60}H_n[NH(CH_2)_mC(O)O]_n$ wherein m is an integer, preferably 3 and 5 (**in sentences 7 of claim 1**). Given that the term “preferably” implies that such limitation is not essential or not necessarily required in the claim, such term renders the claim indefinite. As a result, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claims are unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art.

Art Unit: 1617

However, for the purpose of examination, Examiner will construe that the stated "m" is any integer which can include integers above 5 and lower than 3 and any integers in between 3 and 5.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gan et al. (Chinese Chemical Letters, 1994, Vol. 5, No. 4, pgs. 275-278).

It is respectfully pointed out that the recitation "for inhibiting membrane virus reproduction" has not been given patentable weight because the recitation occurs in a "compound" and "composition". A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robbie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Art Unit: 1617

Gan et al. teach water-soluble fullerene derivatives that are air-stable (see abstract and pg. 277, last paragraph). In particular, Gan et al. teach that β -alanine sodium salt reacts with C_{60} to give a water-soluble derivative A: $C_{60}(NHCH_2CH_2COO^-Na^+)_x(H)_x$ (see pg. 276, top paragraph). Additionally, Gan et al. teach that Derivative A can be acidified to yield a derivative B: $C_{60}(NHCH_2CH_2COOH)_x(H)_x$ (see abstract and pg. 276, paragraphs 1-2). Importantly, Gan et al. teach that elemental analysis reveals that x is equal to 9 and this necessarily reads on the claim limitation where m is 2 and n is 9 (see pg. 275, abstract and pg. 276, paragraph 2).

Accordingly, the teachings of Gan et al. anticipate claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Gan et al. (Chinese Chemical Letters, 1994, Vol. 5, No. 4, pgs. 275-278) in view of Chiang et al. (U.S.5,648,523).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Gan reference is as discussed above and incorporated by reference herein. However, Gan et al. do not teach the fullerene derivatives in pharmaceutical compositions or formulated as tablets or injections.

Chiang et al. teach fullerene derivatives as free-radical scavengers (see abstract). Importantly, Chiang et al. teach that the fullerene derivatives can be prepared as pharmaceutical formulations which contain an excipient (see col. 5, lines 5-7 and col. 6, lines 26-29). In particular, Chiang et al. teach that the active ingredients can be associated with a carrier which constitutes one or more accessory ingredients (see col. 6, lines 39-43). Chiang et al. further teach that the formulations can be made as tablets or powders wherein the active ingredients are blended with finely divided solid carriers which necessarily include fillers (see col. 6, lines 44-47).

Art Unit: 1617

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to formulate the fullerene derivatives of Gan et al. as pharmaceutical compositions and formulate them in the form of tablets and injections given that Chiang et al. teach formulations of fullerene derivatives as pharmaceutical compositions and in the form of tablets. Moreover, one of ordinary skill in the art would have found it obvious to formulate the compositions as suppositories or injections since these types of formulations are well-known formulations in the pharmaceutical art. Thus, given the teachings of Gan and Chiang, one of ordinary skill would have been motivated to formulate the derivatives of Gan as pharmaceutical compositions and in the form of tablets with the reasonable expectation of providing fullerene derivatives that are soluble in water and air-stable.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629.

Art Unit: 1617

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

01/02/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617